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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/696,536 | 10/29/2003 | Leonard M. Patt | 480048.458 | 7818 |

500 7590 03/07/2006

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| EXAMINER |
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HEARD, THOMAS SWEENEY

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| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/696,536

Applicant(s)

PATT, LEONARD M.

Examiner

Thomas S. Heard

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/17/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 3-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 20-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17, 2006 has been entered.

Claims 1-52 are pending with claims 3-19 being withdrawn from consideration for reason of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicant's arguments filed February 17, 2006 have been fully considered but they are not persuasive. Claims 1, 2, and 20-52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pallenberg et al (U.S. Patent 5,538,945), Pickart (U.S. Patent 4,760,051), Pickart (U.S. Patent 5,118,665), Kelly, G.S. Alternative Medicine Review (1998) and Atrium Biotechnologies product information brochure.

Applicants have argued that neither Kelly nor Atrium Biotechnologies teach that (i) cartilage extracts, such as MDI Complex, or (ii) all glycosaminoglycans, in general

have anti-inflammatory activity. Further, Applicants argue that “Kelly teaches that chondroitin sulfates, which are one class of glycosaminoglycans (GC), are required for the formation of proteoglycan found in joint cartilage and, similar to glucosamine sulfate, do not inhibit the enzymes involved in inflammation (see, e.g., the fifth paragraph on page 29 and the first three 111 paragraphs on page 33 of Kelly).” Accordingly, the Applicants argue that, “under the Examiner's rationale (i.e., the combination of components having similar utility), Kelly would actually teach away from the claimed composition and with respect to Atrium Biotechnologies no mention of” [anti-inflammatory activity is cited].

The fact that the Applicants argue that chondroitin sulfates are but one class of GCs is true, but it is still present in MDI complex and shark cartilage along with all the other GCs. With regard to GCs not having anti-inflammatory effects, the Examiner would like to point out that the information relied upon by the Applicants to make their argument from page 33 of Kelly is incomplete. Reading on in the first two paragraphs of page 33, Kelly states that GCs do not have NSAID activity, which inhibit inflammation through cyclooxygenase. But, Kelly states in the next paragraph, “Since the anti-inflammatory ability of GC is different than that of NSAIDs” does not teach away but clearly indicates that GCs have anti-inflammatory activity, just one in which the anti-inflammatory mechanism is different from the commonly known NSAIDS. Finally, the Atrium reference was relied upon for stating that the MDI Complex was composed of glycosaminoglycans and the fact that it did not mention that GCs had anti-inflammatory effects is irrelevant. It is believed that the Examiner has provided the requested support

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for the fact that GCs contained in shark (fish) cartilage and the MDI Complex have anti-inflammatory activity.

Conclusion

No claims are allowed

All claims are drawn to the same invention claimed in the earlier Office Action and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier Office Action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

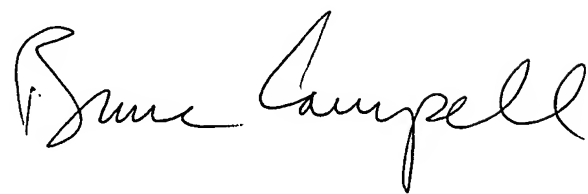
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TSH

A handwritten signature in black ink, reading "Bruce Campell". The signature is written in a cursive, flowing style.

**BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**